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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,882

10/19/2004

Bodo Kuklinski

SONN:057US

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EXAMINER

SCHUBERG, LAURA J

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/511,882

Applicant(s)

KUKLINSKI ET AL.

Examiner

Laura Schuberg

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 10 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/05/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 10, 14-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al (WO 01/97634 A1).

Amended claim 9 is now drawn to a method of treating or preventing neurodermatitis or psoriasis in a subject comprising: obtaining a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix, and orally administering the composition to a subject.

Claim 10 is drawn to the method of claim 9, wherein the subject is a human.

Claim 14 is drawn to the method of claim 9, wherein the matrix is a highly disperse silicon dioxide.

Claim 15 is drawn to the method of claim 9, wherein the mare milk concentrate

Art Unit: 1657

was dried at a temperature of from 10 to 50°C.

Claim 16 is drawn to the method of claim 15, wherein the mare milk concentrate was dried at a temperature of from 35 to 40°C.

Claim 17 is drawn to the method of claim 9, wherein the mare milk concentrate was dried at a pressure of from 1 to 50 mbar.

Claim 18 is drawn to the method of claim 17, wherein the mare milk concentrate was dried at a pressure of from 10 to 30 mbar.

Claim 19 is drawn to the method of claim 9, further comprising drying the mare milk concentrate on the matrix.

Claim 20 is drawn to the method of claim 9, wherein the composition further comprises at least one essential fatty acid.

Claim 21 is drawn to the method of claim 20, wherein the essential fatty acid is a vegetable essential fatty acid.

Claim 22 is drawn to the method of claim 9, wherein the composition further comprises at least one of hydrogen carbonate, potassium, carbonate, citrate, calcium, magnesium, vitamin C, vitamin E, niacin, zinc, iron, beta-carotene, pantothenic acid, manganese, vitamin B6, vitamin B2, vitamin B1, copper, sodium, biotin, folic acid, molybdenum, selenium, xanthan, fructose, citric acid, or vitamin B 12. (Applicant has elected vitamin B1.)

Fuchs teaches an oral composition comprising highly unsaturated fatty acids on a biologically inert matrix (p.9) and drying the composition at a pressure of 10-30 mbar and a temperature of 30-36 ° C (p.12). The reference also teaches that it is

Art Unit: 1657

advantageous to add mare's milk before drying and that dry concentrates of mare's milk have immunostimulatory effects on humans (p.15). It is also taught that it is especially advantageous if the composition is applied on a highly dispersed silicon dioxide matrix (p.12). The composition taught by the reference also contains linolenic acid (p.20), which is a vegetable essential fatty acid. Vitamin B1 is present in mare's milk and therefore inherently present in the composition. Fuchs teaches that highly unsaturated fatty acids are of a high biological and nutrition-medical relevance, especially for skin metabolism, neurodermatitis and psoriasis (p.3) and that the composition taught contains at least one unsaturated fatty acid. The disclosure of the skin disorders, neurodermatitis and psoriasis, and their connection with the need for the highly unsaturated fatty acids would indicate that administration of the referenced composition, which contains highly unsaturated fatty acids, would be necessary. In addition, the reference does teach where the subject is human and that the dry concentrates of mare's milk have beneficial immunostimulatory effects on humans (p.15).

One of ordinary skill in the art would have been motivated to use the composition of Fuchs for the treatment and prevention of dry skin diseases such as neurodermatitis and psoriasis since the highly unsaturated fatty acids in the composition are taught by Fuchs to be important for skin metabolism and these skin disorders (p.3). One of ordinary skill in the art would have had a reasonable expectation of success since Fuchs provides a composition that ensures a fine surface distribution of the oil particles so that sufficient quantities of unsaturated fatty acids are included (p.7).

Therefore, Fuchs renders obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments filed 10/11/2006 have been fully considered but they are not persuasive. One of ordinary skill in the art would not have been motivated to use nor have a reasonable expectation of success in a method of treating or preventing neurodermatitis or psoriasis in a subject by orally administering a composition comprising a mare milk concentrate dried on a biologically inert disperse matrix to the subject in view of the disclosure in Fuchs that a dried, mare milk concentrate has immunostimulatory properties. Applicant argues that a person of ordinary skill in the art would expect that the treatment or prevention of neurodermatitis and psoriasis would require immunosuppressive substances, not immunostimulatory substances. Applicant asserts that Fuch's disclosure that dried mare's milk concentrate has immunostimulatory properties actually teaches away from the claimed invention. Applicant asserts that it is surprising and unexpected that dried mare's milk concentrate would result in the treatment or prevention of neurodermatitis or psoriasis.

This is not found persuasive because the Fuch's reference clearly suggests that the referenced composition would be advantageous for the treatment of neurodermatitis or psoriasis. Fuch's statement that "these (highly) unsaturated fatty acids are very important in biological and clinical nutrition medicine, especially for ... the skin metabolism (neurodermatitis, psoriasis)..." (page 3) clearly shows the intention of using the reference composition in the treatment of these specific skin diseases. There is no mention of neurodermatitis or psoriasis requiring immunosuppressive substances in the

Art Unit: 1657

Fuch's reference and no suggestion of teaching away from the treatment of these skin diseases at all with regard to the reference composition. This reference clearly renders prima facie obvious Applicant's invention as claimed.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

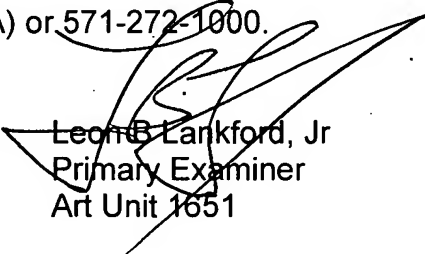
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

Art Unit: 1657

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651

Laura Schuberg